CASE STUDIES

CASE STUDY 2

BACKGROUND

A CLUSTER-RANDOMIZED CONTROLLED TRIAL ON THE EFFECTIVENESS OF AN EDUCATIONAL INTERVENTION DELIVERED THROUGH THE HEALTH SERVICES TO IMPROVE NUTRITION IN YOUNG CHILDREN

The government of Peru operates several types of health facilities that serve the people living in its peri-urban shanty towns, which are characterized by poor housing, a general lack of one or more essential services (*e.g.*, piped water, reliable electrical supply, sewage disposal), and inhabitants with low and insecure income. Most families have access to various nutritious foods, so acute malnutrition (*i.e,* low weight for height) is unusual in children, but anemia and growth-faltering (leading to stunted growth) are common.

To test means of improving the nutritional status of young children, the regional health authority in Trujillo (a city 400 km north of Lima with a population of 600,000) undertook a cluster-randomized trial. Three types of facilities serving Trujillo's periurban communities– community hospitals offering maternal and peri-natal specialist services; health centers with medical staff always in attendance; and health centers with more limited services–were included (facilities offering unique services were excluded from the study.)

The intervention began at the facility level; its implementation process and the effect of the intervention on child outcomes were studied by following cohorts of children from birth to age 18 months, with a final survey at the end of the experiment. The aim was to see whether, in the health facilities assigned to the intervention-arm of the study, the profile of nutrition was raised and nutrition services were integrated into existing childoriented national programmes such as immunization, monitoring of growth and development, and management of acute respiratory infections and diarrhea. The intervention consisted of:

- Enhancing the quality of nutrition counseling through staff training and the provision of simple, standardized, age-appropriate messages to be used at all points of contact with young children in the facility. (These messages were: a thick puree satisfies and nourishes your baby, equivalent to three portions of soup; at each meal, give puree or thick-food preparation first; add a special food to your baby’s serving, (chicken) liver, egg, or fish; and teach your child to eat with love, patience, and good humor.)
- Assisting facilities in developing their own protocols for use of the educational materials.
- Designing clinical history forms to help prompt physicians to include brief questions and advice on nutrition, and training to improve anthropometry skills in health-care workers.
- Demonstrating the preparation of complementary foods, so that facilities could run group sessions for caregivers of children of similar ages to enhance the coverage and nutritional content of the growth-and-development-monitoring programme in well-baby clinics.

It was hypothesized that the intervention would lead to improved feeding practices, dietary intakes, and growth of children in the catchment areas of the intervention health facilities. The primary outcome was growth measured by weight, length, and *Z* scores for weight-for-age and length-for-age at age 18 months, as assessed by fieldworkers. Secondary outcomes were the proportion of children receiving recommended feeding practices and the 24-h dietary intake of energy, iron, and zinc from complementary foods at ages 6, 9, 12, and 18 months. A cohort of newborns was randomly assigned after a census of each health facility's catchment population.

QUESTIONS

1. Families who participated were informed of the study protocol and signed consent was obtained, but they were not told whether they were in the intervention or control group. Is individual consent necessary? What if it Might add a selection bias to the study?

2. How can informed consent be obtained at the level of community in this scenario?

3. When there is no mechanism for opting in or opting out, how does one ensure that participation in a cluster-randomized trial is fair?

4. In answering the foregoing questions, do the characteristics of the intervention being investigated make a difference - that is, whether it is a medical service vs. another type of service, whether it might introduce a new risk or ameliorate an existing one, and the degree and likelihood of harm involved for participants?

5. Should alternate options be offered to families that decline to participate in such a trial?

6. Should there be some benefit for the participants once the trial is over?

DISCUSSION

(Thanks to Dr Arshi Farooqui and Dr. Zulfiqar A. Bhutta, Aga Khan University, for compiling this discussion of Case Study 2)

The first discussion point on this case study was on “equipoise” and whether there is any justification to conduct a cluster randomized trial on this topic because the premise that improving the knowledge would ultimately impact the outcome anyway. There was a lack of clarity among the participants regarding the hypothesis of the case study. The hypothesis of this research was to find the feasibility of health system’s approach to provide feasible nutrition education that could be skilled up to population level subsequently.

It was also discussed that whether individual informed consent is necessary in such situations, most discussants agreed that it is mandatory to take informed consent from the mothers and specifically communicate them that there will be two arms of trial however, discussants agreed that it is not necessary to tell the research participants which arm they are in because it would jeopardize the results. There was also a show of hand on whether researchers should mention in which arm the participant is falling. Vast majority of forum discussants maintained that this information should not be passed to the research participants because revealing will destroy the whole experiment. As far as obtaining informed consent from the community is concerned, most of the discussants thought that it’s an obligation of the researcher to take an assent for accessing these communities but full consent is not mandatory in such situations. An important concern was raised regarding the need of consent from health workers because they were also the target of intervention. It was clarified that consent was taken from the health services workers. Interestingly, in one situation a workers’ rejection was over ruled by the health authorities but this is the way most of the public health authorities works.

Similarly, an interesting finding shared was that even after best of explanation to research participants regarding the blinding and randomization and subsequent reassurance from the participants that they have understood it fully yet it is not infrequent to find out that the majority of the participant will ultimately say “I trust my doctor; he must have chosen the best for me” however, with cluster randomization, at least, this communication challenge could be surpassed.

Opting-out as a deliberate attempt was not considered in this case study however; incidentally in the selected clusters, other health facilities were also available which could have been accessed if participants chose to opt-out from this trial. Opting-in was the main worry for the researchers because participants could feel that things were better in the intervention arm. Some of the discussant raised their concern over the fairness issue in cluster randomized trial which is further complicated by non availability of viable alternatives; however, discussion on this issue remained inconclusive. One group argued hypothetically that if there a situation in which the offered intervention is highly risky but there is also big benefit as well, under such notion, cluster randomized trial might be unacceptable if only community consent is sought. In such situation, individual consent is mandatory within each cluster. It was also suggested that the least acceptable standard for everybody should be the standard of care so that nobody is falling below the standard of care.

A concern was raised that the discussion on current case study is revolving around the randomization issue. However this is not the only study design available. We can compare this year with the last year, from this part of the country to another part of the same country or another country, the whole discussion is taking a shape that randomization is the only viable option, this is wrong and should be rejected and everything may not supposedly be put in that gold standard.

It was also mentioned that currently there is lack of clarity on many of these healthsystems interventions. There lies a dilemma if these large scale interventions are implemented, without being tested through experimental designs, will ultimately end up by exposing population to much greater risk of harm from these half baked whimsical interventions. The solution for such large scale interventions is that these trials should be introduced either through a phased design or through an allocation whereby people have looked at the hard outcome and are convinced that this can be implemented.

Definition of ‘research community’ was also discussed and according to the experts, just defining a community on the basis of geographic area is certainly a mistake. There are several groups that could form research community including; sharing certain economic conditions, based on diseases etc.

There was consensus on the issue that alternate mode of treatment should be provided to families who decided not to participate in this research study and that the researcher has more responsibility to research participants. It was also recommended that at least minimal standard of care should be available for those people who decide to opt-out.

There was also a consensus on the point that the result of the trial should be shared by the participant communities because sharing is beneficial for them in either case.

It was thought that researchers should consult with the community at the time of developing research protocol in order to incorporate or modify the study design in line with community need. Similarly for setting up the research agenda for the community, we can think of many layers which include the researchers, government organization, NGOs and above all, the community itself.

Another important issue discussed was the capacity of Ethics Review Committee for reviewing the public health research proposals because these researches deal with large populations, not on the individual basis. So it was felt that Ethics Review Committee should be trained in dealing with public health research proposals.